



# PROPOSED RULE MAKING

## CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

**Agency:** Washington State Liquor and Cannabis Board

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> Preproposal Statement of Inquiry was filed as WSR 16-17-149 ; or | <input checked="" type="checkbox"/> Original Notice       |
| <input type="checkbox"/> Expedited Rule Making--Proposed notice was filed as WSR _____ ; or          | <input type="checkbox"/> Supplemental Notice to WSR _____ |
| <input type="checkbox"/> Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).                  | <input type="checkbox"/> Continuance of WSR _____         |

**Title of rule and other identifying information:** (Describe Subject)  
New Section WAC 314-55-073, Marijuana research license.

**Hearing location(s):**

Washington State Liquor and Cannabis Board  
Board Room  
3000 Pacific Ave SE  
Olympia, WA 98504

Date: December 28, 2016 Time: 10:00 am

**Submit written comments to:**

Name: Joanna Eide, Policy and Rules Coordinator  
Address: PO Box 43080  
Olympia, WA 98504  
e-mail [rules@lcb.wa.gov](mailto:rules@lcb.wa.gov)  
fax (360) 664-9689 by (date) December 28, 2016

**Assistance for persons with disabilities:** Contact

Joanna Eide by December 21, 2016

TTY ( ) \_\_\_\_\_ or (360) 664-1622

**Date of intended adoption:** on or after January 11, 2017  
(Note: This is NOT the effective date)

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:** The purpose of this proposal is to implement the application process, review process, and requirements for the marijuana research license as established in RCW 69.50.372.

**Reasons supporting proposal:** Rule changes are needed to implement the marijuana research license established by RCW 69.50.372. Changes to RCW 69.50.372 were passed by the Legislature during the 2016 legislative session making it possible for the WSLCB to proceed with implementing the new license. RCW 69.50.372 gives the WSLCB authority to adopt rules related to the implementation of the marijuana research license in RCW 69.50.372(5), including application requirements and administrative provisions relating to the license. These rules are needed to fully implement and issue the license.

**Statutory authority for adoption:** RCW 69.50.342, 69.50.345, and 69.50.372

**Statute being implemented:** RCW 69.50.342, 69.50.345, and 69.50.372

**Is rule necessary because of a:**

- |                         |                              |  |
|-------------------------|------------------------------|--|
| Federal Law?            | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Federal Court Decision? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| State Court Decision?   | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
- If yes, CITATION:

**CODE REVISER USE ONLY**

OFFICE OF THE CODE REVISER  
STATE OF WASHINGTON  
FILED

**DATE: November 17, 2016**

**TIME: 3:15 PM**

**WSR 16-23-105**

**DATE**  
November 17, 2016

**NAME** (type or print)  
Jane Rushford

**SIGNATURE**

**TITLE**  
Chair

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:**  
**None.**

**Name of proponent:** (person or organization) Washington State Liquor and Cannabis Board

- Private  
 Public  
 Governmental

**Name of agency personnel responsible for:**

Name	Office Location	Phone
Drafting..... Joanna Eide, Policy and Rules Coord	3000 Pacific Ave SE, Olympia, WA 98504	(360) 664-1622
Implementation....Rebecca Smith, Licensing Director	3000 Pacific Ave SE, Olympia, WA 98504	(360) 664-1615
Enforcement..... Justin Nordhorn, Chief Enforcement	3000 Pacific Ave SE, Olympia, WA 98504	(360) 664-1726

**Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?**

Yes. Attach copy of small business economic impact statement or school district fiscal impact statement.

A copy of the statement may be obtained by contacting:

Name: Joanna Eide, Policy and Rules Coordinator

Address:

3000 Pacific Ave SE

Olympia, WA 98504

phone (360) 664-1622 \_\_\_\_\_

fax (360)664-9689 \_\_\_\_\_

e-mail [Joanna.Eide@lcb.wa.gov](mailto:Joanna.Eide@lcb.wa.gov) \_\_\_\_\_

No. Explain why no statement was prepared.

**Is a cost-benefit analysis required under RCW 34.05.328?**

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name:

Address:

phone ( ) \_\_\_\_\_

fax ( ) \_\_\_\_\_

e-mail \_\_\_\_\_

No: Please explain: A cost-benefit analysis was not required under RCW 34.05.328 because the proposed new rule does not qualify as a significant legislative rule or other rule requiring a cost benefit analysis under RCW 34.05328(5).



Washington State  
**Liquor and Cannabis Board**

---

**Date:** November 16, 2016

**To:** Jane Rushford, Board Chair  
Ollie Garrett, Board Member

**From:** Joanna Eide, Policy and Rules Coordinator

**Copy:** Rick Garza, Agency Director  
Justin Nordhorn, Chief of Enforcement  
Becky Smith, Licensing Director  
Karen McCall, Agency Rules Coordinator  
Tim Gates, Marijuana Examiners Unit

**Subject: Small Business Economic Impact Statement  
Marijuana Research License**

A small business economic impact statement has been prepared under chapter 19.85 RCW.

Small Business Economic Impact Statement:

**WAC 314-55-073 Marijuana research license.**

**1. Description of reporting, record keeping and other compliance requirements of the proposed rule:**

WAC 314-55-073, Marijuana research license, is a proposed new WAC section that details application requirements and other requirements for marijuana research license holders. It contains several reporting and other compliance requirements, which apply to all applicants and licensees. The rule also details requirements for the WSLCB's scientific reviewer regarding review of applications, research projects, and ongoing review and reporting.

- a. The following requirements apply to all applicants:
  - i. Detailed application requirements including demonstrating the scientific basis for research proposals;
  - ii. Facility requirements, including security requirements;
  - iii. Criminal background checks; and
  - iv. Financial investigations.



## Washington State Liquor and Cannabis Board

---

- b. The following requirements apply to all holders of a research license:
  - i. Security requirements similar to those requirements for other marijuana licensees to ensure marijuana is not diverted to the illegal market;
  - ii. Prohibition of comingling of marijuana on site held for purposes other than research;
  - iii. Tracking of marijuana obtained and possessed for research purposes through the state's traceability system;
  - iv. Review and approval of any additional research projects under the license prior to obtaining marijuana and conducting research for those projects;
  - v. Project status reporting applying to both license holders and the WSLCB's scientific reviewer;

### **2. Kinds of professional services that a small business is likely to need in order to comply with such requirements:**

There are no mandatory professional services applicants or licensees will need in order to comply with the requirements. Applicants or licensees may choose to obtain professional services, but this will be voluntary in nature and may depend on the type of research the applicant or licensee intends to conduct.

### **3. Costs of compliance for businesses, including costs of equipment, supplies, labor and increased administrative costs:**

Since this is a new license and a voluntary license, there are no costs that will apply across the board to businesses the WSLCB regulates or small businesses unless and until they choose to apply for a research license. Costs for equipment, supplies, labor and administrative costs will depend on the type of research and specific research project the applicant or licensee intends to conduct. Once licensed, research licensees will have access to the state's traceability system at no cost.

### **4. Will compliance with the rules cause businesses to lose sales or revenue?**

Rule requirements should not cause loss of sales or revenue. The research license is intended to generate scientific research and data regarding cannabis, but may also be used for commercial purposes. The WSLCB anticipates that laboratories that already conduct other types of research will apply for the research license, so adjustments for marijuana research should be minimal in those cases and should not result in loss of sales or revenue.

### **5. Costs of compliance for small businesses compared with the cost of compliance for the ten percent of businesses that are the largest businesses required to comply with the proposed rules using one or more of the following as a basis for comparing costs:**

- a. Cost per employee;



- b. Cost per hour of labor; or**
- c. Cost per one hundred dollars of sales**

Businesses vary in size, costs per employee, costs per hour of labor, and costs per one hundred dollars in sales for a multitude of reasons, including license type if an applicant is a licensed marijuana business. The costs for compliance will vary significantly depending on the applicant, category of research proposed (see RCW 69.50.372), and complexity of the research project. For these reasons, and because it is unclear as to how many persons or entities will apply for the license and the size of any businesses that choose to apply, costs for compliance are indeterminate.

**6. Steps taken by the agency to reduce the costs of the rule on small businesses, or reasonable justification for not doing so:**

The WSLCB sought to reduce costs on licensees through making the application process electronic in nature and by clearly delineating application and ongoing requirements in the proposed rule. The WSLCB will work with the scientific reviewer regarding costs for review once a scientific reviewer is selected as applicants and licensees will be responsible for paying costs of review directly to the scientific reviewer as required by RCW 69.50.372. Review costs will be varied depending on the types of projects that are proposed. Each research project will be different in subject, scope, and detail. Costs incurred for review will depend on the number of projects proposed and the complexity of the research project proposal. The WSLCB will provide access to the state's traceability system at no cost to research licensees.

Because marijuana research licensees will be dealing with a Schedule I listed substance on both a state and federal level, and the WSLCB is tasked with ensuring the security of marijuana and preventing diversion into the illegal market, a high level of regulatory restriction, oversight, and reporting is appropriate. The WSLCB sought to reduce costs where possible, but has to balance cost reductions against security and traceability considerations, as well as ensure requirements are in place to ensure that licenses are appropriately granted (financial investigations and background checks). For these and other public safety reasons, the costs of compliance with rule requirements are justified.

**7. A description of how the agency will involve small businesses in the development of the rule:**

Stakeholders are invited to provide feedback to the rules during the rulemaking process.

**8. A list of industries that will be required to comply with the rule:**

All applicants for a marijuana research license and marijuana research license holders will be required to comply with these rules. Applicants could range from a multitude of industries, including from the scientific, educational, agricultural, or commercial



## Washington State Liquor and Cannabis Board

---

industries. Licensed marijuana businesses who choose to apply for a license will also be required to comply with the rule requirements. All persons or entities that receive a research license will have to meet ongoing conditions of licensure and reporting requirements.

The WSLCB's scientific reviewer will also have to comply review and reporting requirements as part of administering the marijuana research license program. The WSLCB is currently in the process of soliciting applications for a scientific reviewer.

### **9. An estimate of the number of jobs that will be created or lost as a result of compliance with the proposed rule:**

Indeterminate. It is unknown how many persons or entities will apply for a research license at this time and what types or sizes of businesses, organizations, or other entities with employees will apply for a license.

NEW SECTION

**WAC 314-55-073 Marijuana research license.** A marijuana research license allows a holder of the license to produce, process, and possess marijuana for the limited research purposes provided in RCW 69.50.372. The WSLCB designates a scientific reviewer (reviewer) to review research applications and make recommendations for the approval or denial of research projects and to assess licensed research activities. The following provisions are in addition to the requirements for marijuana research licensees provided in RCW 69.50.372.

**(1) Eligibility and continuing requirements for research license applications, prohibitions and restrictions.**

(a) Other than the restrictions listed in this subsection, any person, organization, agency, or business entity may apply for a marijuana research license.

(b) Other marijuana licensees may apply for a research license. Facilities at which the research is conducted must be wholly separate and distinct from the marijuana business, except:

(i) Licensed producers with a research license and approved research project may grow marijuana plants or possess marijuana for research purposes at the producer's licensed premises. However, all marijuana grown or possessed for research purposes or purposes other than those related to the research project must be kept wholly separated and distinct from commercial operations and must not be comingled with or diverted to marijuana grown for commercial purposes or purposes other than those related to the research project; and

(ii) Licensed processors with a research license and approved research project may possess marijuana for research purposes at the processors licensed premises. However, all marijuana possessed for research purposes must be kept wholly separated and distinct from all marijuana possessed for commercial purposes or purposes other than those related to the research project and must not be comingled with or diverted to marijuana possessed for commercial purposes or purposes other than those related to the research project. Licensed processors who do not also hold a producer license may not grow marijuana plants for the purposes of research under a research license at the processor's licensed location.

(c) Labs certified to perform quality assurance testing on marijuana and marijuana products by the WSLCB may apply for a research license. Certified labs with a research license and approved research project must ensure that all marijuana possessed for research purposes is wholly separated from and is not comingled with marijuana possessed for state required testing purposes for licensed producers or processors or marijuana possessed for any reason other than research purposes.

(d) All research license applicants and persons conducting research under the research license must be twenty-one years of age or older.

(e) All research license applicants and those persons that have managing control over an organization, agency, or business entity must pass a criminal background check and financial investigation prior to being eligible to receive a research license.

(f) No applicant for a research license may possess any marijuana plants or marijuana unless and until the research project is approved and the applicant is notified that the research license is approved in writing by the WSLCB.

(g) No research licensee may conduct research unless and until the research project is approved by the reviewer and the WSLCB in writing.

(2) **Initial applications.**

(a) **Application made with business licensing services (BLS).**

(i) Applicants for a research license must apply through BLS to begin the application process for a research license.

(ii) Upon submitting an application for a research license through BLS, the applicant will receive an application letter from the WSLCB directing the applicant to submit the additional application materials directly to the WSLCB's designated scientific reviewer (reviewer).

(A) The applicant must submit complete and accurate additional application materials directly to the reviewer within thirty days of the date of the application letter from the WSLCB or by the date indicated on the application letter. It is the responsibility of the research license applicant to comply with the application requirements in this section and ensure the application is complete, accurate, and successfully submitted to the reviewer.

(B) Incomplete or incorrect additional application materials, materials that do not adhere to the content requirements in this section, or materials not received by the reviewer by 5:00 p.m. on the 30th day or the application date as indicated on the letter from the WSLCB will not be considered by the reviewer and the WSLCB will withdraw the application after receiving notice in writing from the reviewer.

(b) **Additional application materials requirements.**

(i) Application materials that do not adhere to the content requirements in this section or incomplete or incorrect applications will be withdrawn.

(ii) The applicant is responsible for ensuring that no information is included in the research plan that may compromise the applicant's ability to secure patent, trade secret, or other intellectual property protection. All application documents must be submitted by a person who has the legal authority to represent the entity if the applicant is an entity other than an individual person.

(iii) All documents must be submitted to the reviewer in a legible PDF format.

(iv) All of the following information and documents are required for each initial application:

(A) A completed cover page form, marijuana research license application form, and signature page form created by the WSLCB and available at the WSLCB's web site at [www.lcb.wa.gov](http://www.lcb.wa.gov).

(B) A research plan limited to four pages that includes the following information:

(I) Purpose and goal(s) of the proposed research project(s);

(II) Key milestones and timelines for the research project(s);

(III) Background and preliminary studies;

(IV) Amount of marijuana to be grown, if applicable, including the justification with respect to milestone tasks;

(V) Anticipated cost of the proposed research project(s) and funding available for the work;

(VI) Key personnel and organizations, including names and roles;

(VII) Facilities, equipment, and other resources required and available for conducting the proposed research project(s).

(C) A biosketch for each individual involved in executing the proposed research project limited to two pages per individual perform-

ing technical and administrative functions essential to performing the proposed research, including proof that the individual is twenty-one years of age or older. Biosketches must be prepared using the National Institutes of Health (NIH) biographical sketch format, available at <http://grants.nih.gov/grants/forms/new-renewal-revisions.htm>.

(D) Letters of support limited to two pages per letter confirming the commitment of time and resources from external personnel or organizations if external personnel or organizations will participate in research activities under an approved research project. Letters of support are required to confirm the commitment of time and resources from personnel involved in the proposed research project(s) who are not employed at the applicant organization. Letters of support must include specific details regarding the type(s) and magnitude of the time and resources being committed to the proposed research project(s) and must be signed by individuals having the authority to make such commitments.

(E) For all project(s) involving human or animal subjects, documentation of all required institutional review board (IRB) or institutional animal care and use committee (IACUC) approvals. Documents must be provided on IRB or IACUC letterhead and be signed by authorized officials of those regulatory bodies.

(v) Documents that do not conform to the requirements in subsection (b) of this section may be withdrawn. All nonform documents must conform to the following requirements:

(A) Eight and one-half by 11-inch portrait-oriented page dimensions;

(B) Single-spaced with all margins measuring at least one inch; and

(C) At least 12-point font in Times New Roman or Arial, not proportionately reduced.

(c) **Review by the WSLCB's designated scientific reviewer.**

(i) If the applicant submits application materials to the reviewer by the required deadline specified by the WSLCB's application letter and the reviewer determines the additional application materials are complete and meet the document requirements specified in this section, the reviewer will proceed with reviewing the research project to evaluate whether the project complies with the provisions of RCW 69.50.372 (1) and (2).

(ii) When evaluating research projects, the reviewer must:

(A) Ensure confidentiality; and

(B) Screen members of the reviewer panel for any conflicts of interest and take appropriate measures if a conflict of interest is identified.

(iii) The reviewer will assess fees for the review of the research project proposal directly to the applicant pursuant to RCW 69.50.372(7). The reviewer will not recommend approval of an application for any research license for which an unpaid balance of fees to the reviewer is due regardless of the recommendation of the reviewer regarding the sufficiency of the research project.

(iv) If at any time during the process of review the reviewer finds that the additional application materials are not complete, the reviewer will notify the WSLCB in writing and the WSLCB will withdraw the application.

(v) The reviewer will supply a written evaluation to the WSLCB in writing after completing review of the research project. Evaluations will provide the approval recommendation status; determination(s) of the applicable research category or categories; and, as applicable,

the reasons for a "Not Approved" recommendation. The WSLCB will provide written evaluations to applicants following completion of the review process by the reviewer along with the WSLCB's approval or denial of the research license.

(d) **WSLCB requirements and licensing process.** If the reviewer indicates the application for a research license should be approved, the following requirements must be met prior to final approval of the license by the WSLCB.

(i) The WSLCB will request criminal background and financial information from the research license applicant and evaluate the applicant(s) pursuant to the standards and requirements established in WAC 314-55-020;

(ii) The applicant(s) must adhere to the notice posting requirements under WAC 314-55-020;

(iii) The applicant must demonstrate access to and proficiency with the traceability system; and

(iv) The applicant must meet facility security requirements as provided in WAC 314-55-083 prior to being granted a license.

(3) **Research license withdrawal and denials.**

(a) The WSLCB will withdraw an application if:

(i) The application or additional application materials are determined incomplete or incorrect by the WSLCB or its designated reviewer;

(ii) The additional application materials are not timely received by the reviewer as provided in this section; or

(iii) The applicant(s) request withdrawal of a research license application at any time in the application process. The applicant must request the withdrawal in writing and is responsible for any review costs due to the reviewer. The voluntary withdrawal of a research license application does not result in a hearing right.

(b) The WSLCB will deny a research license if:

(i) The scientific reviewer does not recommend approval of the license after reviewing the research proposal for compliance with this section or RCW 69.50.372;

(ii) The applicant does not meet the requirements for a license under this section or RCW 69.50.372; or

(iii) The applicant provides false or misleading information in any of the materials it submits to the WSLCB or the reviewer.

(c) If the WSLCB denies a research application for the reasons provided in (b)(iii) of this subsection or for failing to meet criminal history or administrative violations requirements under this section, the applicant(s) is prohibited from reapplying for a research license for one calendar year from the date of the WSLCB's denial of the license.

(d) A person or entity that has outstanding unpaid review fees owing to the scientific reviewer is prohibited from reapplying for a research license until all review fees are paid to the scientific reviewer.

(4) **Reporting required.**

(a) The WSLCB or the WSLCB's designated reviewer may require reporting by or auditing of research licensees as necessary.

(b) The WSLCB's designated reviewer must submit an annual status report of all completed and ongoing research projects for the previous year to the WSLCB by December 31st of each calendar year.

(c) The licensee must adhere to the reporting requirements in the traceability system under WAC 314-55-083.

(d) The reviewer must immediately notify the WSLCB if it receives information indicating that a research licensee is operating outside the scope of the projects approved under a research license.

**(5) Adding an additional research project or changing existing approved research project process (after licensure).**

(a) A research licensee is restricted to only those research activities under a research project that has been reviewed and approved by reviewer.

(b) Applications to add a new project or change an existing approved project is the same as what is required for initial application except that a new license application through BLS is not required. To apply to add a new research project or change an existing approved project, a research licensee must submit all materials to the reviewer as required under subsection (2)(b) of this section. Incomplete project applications will not be considered.

(c) The reviewer will review the application for a new research project or change to an existing approved research project pursuant to subsection (2)(c) of this section. The reviewer will supply a written evaluation to the WSLCB and the licensee in writing after completing review of the application for a new research project or a change to an existing approved research project. Evaluations will provide the approval recommendation status; determination(s) of the applicable research category or categories; and, as applicable, the reasons for a "Not Approved" recommendation.

**(6) Research license renewals.**

(a) Research license renewals operate on an annual basis, based on the license issuance date. A licensee must have an ongoing approved research project or an application for a new research project to be eligible for license renewal. The WSLCB will notify the licensee and reviewer ninety days prior to the license renewal date. The licensee must provide a status report to the reviewer or an application for a new research project if the licensee's ongoing approved research project will end within thirty days prior to or after the renewal date. The status report or application must be received by the reviewer within thirty days of the ninety-day renewal notice from the WSLCB or the license will not be renewed.

(b) The reviewer will notify the WSLCB in writing if the licensee meets the requirements for renewal not later than fifteen days prior to the licensee's renewal date.

(c) If the reviewer determines that the research project does not meet requirements for renewal due to lack of an ongoing project or for failure to meet the requirements of RCW 69.50.372 or this section for a proposed new project, the reviewer will recommend the WSLCB not renew the license.

(d) The WSLCB will review the licensee's violation history and criminal background check prior to renewal. If the violation history or criminal records disqualifies the licensee from eligibility for a research license under WAC 314-55-050, the WSLCB will not renew the license.

**(7) License revocation.**

(a) The WSLCB may revoke an application for the following reasons:

(i) The WSLCB has reason to believe that marijuana is being diverted from the research licensee;

(ii) The research licensee operates outside the scope of the research project(s) approved under the license issued to the licensee;

(iii) The applicant makes a misrepresentation of fact, or fails to disclose a material fact to the WSLCB during the application process or any subsequent investigation after a license has been issued;

(iv) The WSLCB finds that the licensee possesses marijuana plants, marijuana, or marijuana products that are not accounted for in the traceability system;

(v) The research licensee makes changes to their operating plan, entity structure, or location without prior approval from the WSLCB;

(vi) The research licensee fails to maintain security requirements for the licensed research facility; or

(vii) The licensee violates any provision of chapter 69.50 RCW or this chapter.

(b) A licensee may request voluntary cancellation of a license at any time. The licensee must request cancellation of a research license to the WSLCB in writing. The voluntary cancellation of a research license does not result in a hearing right.

**(8) Marijuana disposal requirements.**

(a) Licensees must dispose of marijuana as provided in WAC 314-55-097.

(b) Licensees must dispose of marijuana if the research license is discontinued for any reason. A licensee may transfer plants to another marijuana research licensee. A licensee may work with the WSLCB to dispose of marijuana or marijuana plants.

(9) An applicant or licensee may request an administrative hearing to contest the withdrawal, denial, nonrenewal, or revocation of a research license pursuant to chapter 34.05 RCW. A request for a hearing must be made in writing and received by the WSLCB no later than twenty days after the date the notification of withdrawal, denial, nonrenewal, or revocation was mailed to the applicant or licensee. Appeal requests submitted in paper form may be delivered to the WSLCB in person during normal business hours at 3000 Pacific Avenue S.E., Olympia, WA 98501, or mailed to the WSLCB. Mailed appeal requests must be addressed to: WSLCB, ATTN: Adjudicative Proceedings Coordinator, P.O. Box 43076, Olympia, WA 98504-3076 or, for certified mail, WSLCB, ATTN: Adjudicative Proceedings Coordinator, 3000 Pacific Avenue S.E., Olympia, WA 98501.